EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO THE FOLLOWING CASES:

Daphne Barker, et al.	2:12-cv-0899
Kathy Barton	2:12-cv-00351
Barbara Bridges	2:12-cv-00757
Carolyn Doyle	2:12-cv-00555
Ann Fuller	2:12-cv-00539
Amelia Gonzales	2:12-cv-00468
Deborah Joplin	2:12-cv-00787
Amy Holland	2:12-cv-00256
Mary Kilday	2:12-cv-00387
Kimberly Lager	2:12-cv-01305
Patti Ann Phelps, et al.	2:12-cv-01171
Maria Eugenia Quijano	2:12-cv-00799
Rhoda Schachtman	2:12-cv-00548
Deanna Thomas	2:12-cv-00601
Lisa Thompson, et al.	2:12-cv-01199
Jennifer Van Rensburg	2:12-cv-00749
Mary Wise	2:12-cv-00571

RULE 26 EXPERT REPORT OF KIMBERLY H. ALLISON, M.D.

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. The opinions which I have concerning the above-listed plaintiffs in *In re: Ethicon, Inc. Pelvic Repair System Products Liab. Litig.*, MDL No. 2327, all of which I hold to a reasonable degree of medical and scientific certainty, are as follows:

I. Qualifications

My name is Kimberly H. Allison, M.D. I am Associate Professor of Pathology at Stanford University Medical Center. My professional activities include diagnostic examination of specimens surgically removed from human patients. I have specialty training in breast and gynecologic pathology and focus on these areas in my clinical work and research but also review general surgical pathology. In my clinical work, I have reviewed over 50,000 pathology specimens and review and report on approximately 200-300 cases/month (surgical specimens, slide reviews, specialty testing and intra-operative consultations) as part of my practice. The specimens I review and report on in clinical practice include explanted medical devices such as vaginal and hernia mesh, breast implants, tissue expanders and other medical hardware.

I am actively involved in resident/fellow training in the practice of pathology both as faculty with teaching responsibilities and as Associate Residency Director for the Department of Pathology. I also co-direct the Stanford Breast/GYN Pathology Fellowship, which focuses on development of specialty expertise in gynecologic and breast pathology.

My research interests include prognostic/predictive markers in breast and gynecologic cancer, HER2 heterogeneity by FISH testing, diagnostic criteria and diagnostic agreement in breast and gynecologic pathology, and the role of the immune system's response to neoplasia. I have also published in gynecologic pathology.

I earned a medical degree at New York Medical College. I earned a Bachelor of Arts (molecular biology) from Princeton University. I was trained in pathology at the University of Washington, Seattle, Washington, where I completed an Anatomic and Clinical Pathology Residency and a Surgical Pathology Fellowship with a focus on breast and gynecologic pathology. I am board certified in Anatomic and Clinical Pathology. Prior to joining the faculty at Stanford University, I was Associate Professor, Director of Breast Pathology Service, Department of Anatomic Pathology, at the University of Washington Medical School.

I was an expert panel member for establishing clinical guidelines for HER2 testing in breast cancer. I am a member of the College of American Pathologists and the United States and Canadian Academy of Pathology. My work has been published in the *Journal of Clinical Oncology, American Journal of Clinical Pathology, Gynecology Oncology, International Journal of Gynecological Pathology, Annals of Surgical Oncology, Obstetrics and Gynecology, Human Pathology,* and *Clinical Cancer Research.* I have authored over fifty peer-reviewed articles, three case reports, three invited reviews, and three book chapters. I routinely present my research and give educational talks and courses at scientific meetings, including meetings of the United States & Canada Academy of Pathology.

My curriculum vitae is attached to this report as **Exhibit A**.

II. General Opinions

Based on my review of the medical and scientific literature and review of the pathology of explanted vaginal meshes, there is evidence that the use of vaginal mesh composed of polypropylene fibers can result in adverse medical outcomes such as chronic pain (including surreptitious irreversible neuralgia or SIN syndrome), dyspareunia, mesh erosion, urinary dysfunction, infection and bowel dysfunction. The mechanisms responsible for the symptoms caused by vaginally placed polypropylene mesh, such as used in the Ethicon products, are related to tissue response to the implanted mesh, continued chronic inflammation and degradation of the mesh while in the body, nerve entrapment/damage in the scar formation around the implanted mesh and development of mesh stiffness (brittleness or hardening) – all of which make it ill-suited for its intended purpose and likely to cause significant harm to patients. (Costello 2007, Iakovlev 2015, Klinge 2013, Klosterhalfen 2004, Bendavid 2014, Riccetto 2008)

When a foreign material is first implanted in the human body, a normal inflammatory process ensues in response to the tissue damage and the foreign substance. Initially, active inflammation and renewed tissue growth occur as part of the healing process. The acute pain resulting from this initial process of damage and repair is related to cytokine release by the inflammatory process as well as any damage that occurred to nerves during the procedure. This should resolve within the first few days to weeks after surgery. The response to foreign material is formation of a histiocytic giant cell reaction, which will continue if the material is too large for engulfment and breakdown by histiocytes. Over a period of a few weeks, the healing process should result in new tissue growth and the inflammatory process should resolve (although the foreign body giant cells alone may persist).

When infection occurs, the active inflammatory process becomes more pronounced, additional tissue damage occurs and the healing process is delayed. When infection is absent but the foreign material is not biologically inert and/or it continues to degrade and release additional irritants, a repetitive tissue injury cycle occurs resulting in a chronic inflammatory process. Chronic inflammation results in a cycle of release of pain-inducing cytokines, release of oxidative free radicals as well as an abnormal scarring process. In the case of polypropylene vaginal mesh, the foreign substance of the mesh can create a chronic inflammatory process which not only contributes to pain by cytokine release, but also contributes to degradation of the fibers (which is readily observed both under the light microscope as “treebarking” as well as under the electron microscope), which then may release more inflammation-inducing substances. The chronic inflammation can cause a dense plate of scar tissue to form around and within the mesh (“encapsulation”) in an abnormal healing process. (Costello 2007, Klinge 2013, Iakovlev 2015)

Scarring and encapsulation of the mesh is part of the body’s attempt to “wall-off” the offending foreign material. A similar form of encapsulation occurs around breast implants, with formation of a new “capsule” of dense fibrous tissue around the implant, often lined by a layer of synovial-type cells similar to those that line a joint. The biocompatible breast implant is then appropriately encapsulated and able to both stay in place and remain somewhat mobile/flexible with little disruption of the surrounding tissues. However, this is not the case with mesh used in the female pelvis. The body’s attempt to “wall off” or encapsulate mesh results in a foreign body

reaction around each polypropylene fiber. The scarring/encapsulation that occur is particularly problematic in the specific anatomic location of the female pelvis; a location that is both heavily innervated and requires tissue flexibility for proper function. Because of the heavy innervation of this area, nerves are frequently entrapped by the fibrosis and tissue ingrowth between and around mesh pores. In my review of mesh removed for symptoms such as dyspareunia and chronic pain, it is common to see small to medium-sized nerves both adjacent to and within the scar-plate formed around the mesh fibers. Others have identified similar findings of small nerves entrapped in the fibrosis around mesh fibers in explants. (Klosterhalfen 2004, Iakovlev 2014, Bendavid 2015) In addition, the scarring and chronic inflammation cause stiffening (or hardening) and contracture of the area containing the mesh, which will result in reductions in the required tissue flexibility of the vagina or damage to surrounding functional structures such as the urethra or anus (resulting in bladder or bowel dysfunction). (Rogowski 2013) Ultrasound data consistently demonstrates 30-60% decreases in mesh size at 4-12 weeks compared with size at insertion. (Garcia-Urena MA 2007; Tunn 2007) In addition to human studies on the frequency of contracture of polypropylene vaginal mesh, case controlled animal studies have also found dramatic increases in the stiffness of explanted vaginal material from animals implanted with polypropylene mesh, such as Ethicon's pelvic organ prolapse and midurethral sling products, when directly compared with vaginal native tissue. (Feola 2014) Reduced flexibility of the normal pelvic tissue and entrapped nerves can result in chronic pain during normal activities and pain with sexual intercourse (dyspareunia). These changes can be permanent because of the severity and irreversibility of the scarring, continuing to cause symptoms even after mesh removal is attempted. (Crosby 2014; Bendavid 2014, Rogo-Gupta 2013)

In addition to pain, mesh erosion and exposure is a frequent complication of POP procedures using polypropylene mesh. Erosions occur due to the fragile nature of the overlying vaginal mucosa, the stiffness of the encapsulated and degrading mesh and the development of distortions or curls in the damaged mesh that cause overlying tissue breakdown. These erosions would not occur without the presence of the mesh. Similar to any open wound on a mucosa-lined surface, mesh-induced vaginal erosions and mesh exposures cause increases in inflammation and increase susceptibility to infection. Mesh-induced vaginal erosions can cause bleeding and abnormal discharge and contribute to chronic pain and dyspareunia (in both the women and their male partners). Erosions can also contribute to the development of fistulas between the bladder or rectum and the vagina.

In my opinion, to a reasonable degree of scientific and medical certainty, the described pathological processes above cause or contribute to the complications experienced by women with transvaginally placed polypropylene mesh. These complications include chronic pain, dyspareunia, mesh erosion, urinary dysfunction, infection and bowel dysfunction. It is my opinion that these complications are the sequelae of the tissue response to the non-inert and degrading mesh with resultant chronic inflammation and scarring. The tissue reactions to the mesh – scarring, nerve entrapment, chronic inflammation and resultant reduced flexibility and functionality of the pelvic organs (vagina as well as bladder and bowel outlets) – are all direct or contributing causes to these women's pain and dysfunction. These changes can be irreversible, resulting in chronic pain and dysfunction even after attempts to remove implanted mesh. It is my opinion that the Ethicon's products were ill-suited for their intended use in the specific anatomic location of the

female pelvis, because of the frequency and potential severity of these complications, which occur as a direct result of tissue reaction to the non-inert mesh material.

For a list of materials reviewed, see **Exhibit B**.

III. Case-Specific Opinions

My job as a surgical pathologist is to examine pathology, take into consideration the materials examined (such as mesh), and make diagnoses from my examination of the pathology and my knowledge of the body and the reactions of human tissue. Other physicians rely on me to diagnose the cause of their patient's problems. In reaching my opinions in these cases, I have employed the same techniques, procedures, methodology, and scientific rigor that are routinely employed in the field of pathology and that I use in my practice.

For my detailed pathology reports, see **Exhibit C**. My case-specific opinions and observations are based upon my knowledge, training, experience, my review of the pathology material and my study of the medical and scientific literature. I have reviewed pathology material from 18 women. It is my opinion that the Ethicon devices were a substantial contributing cause of the injuries experienced by these 18 women. I hold these opinions to a reasonable degree of medical and scientific certainty.

Daphne Barker was implanted with a TVT midurethral sling on April 28, 2009 for stress urinary incontinence. Since that time, she has developed erosion, urinary dysfunction, pelvic pain, and dyspareunia. I understand the she is scheduled to have a revision procedure on February 12, 2016. I have been asked to review the removed mesh and reserve the right to supplement my report when pathology is made available to me.

Kathy Barton was implanted with a TVT-O midurethral sling on December 31, 2008 for the treatment of stress urinary incontinence. On March 26, 2010, Ms. Barton presented with a 4 mm area of exposed mesh below the urethra which was excised in an in-office procedure. Pathology is not available for this procedure. On December 10, 2010, Ms. Barton had another area of exposed mesh (2-3 mm) under the urethra which was noted to be extremely tender. Ms. Barton underwent a surgical revision of the mesh on June 8, 2010. Pathology was not available for review. Should pathology become available, I reserve the right to supplement my findings. In 2011, Ms. Barton presented with another area of erosion at the midline of the sling. She reported pain with intercourse both for her and her partner. On examination, there was tenderness on palpation on both the left and right sides to the pelvic sidewall. Ms. Barton underwent a partial sling removal procedure on April 26, 2011. According to the pathology report, the removed mesh measured 2.5 x 1 x 0.8 cm. On examination, I noted mesh fibers in dense fibrosis and surrounding scar. There was mild chronic inflammation and foreign body reaction to the fibers. There were some intact fibers in tissue with possible focal "treebarking." Slides with S100 staining revealed small nerves entrapped in scar tissue and adjacent to mesh fibers. Slides with trichrome staining confirmed dense fibrosis. From my review of Ms. Barton's medical records and my pathological findings as described here and in Exhibit C, it is my opinion that Ethicon's TVT-O device was the cause of her exposure/erosion, pelvic pain, dyspareunia, and resulting revision procedures.

Barbara Bridges was implanted with a Prolift Total on July 11, 2006 for cystocele, rectocele and enterocele. She developed stress urinary incontinence and was implanted with a TVT-O on September 15, 2006. In November 2013, she presented with erosion at the apex (1 x 3 cm), pelvic pain, dyspareunia, incontinence, incomplete bladder emptying, chronic constipation, recurrent urinary tract infections, urgency, nocturia and hematuria. On December 6, 2013, she underwent a revision surgery. The pathology report from Emory University Hospital described the removed material as anterior vaginal wall mesh, 2.6 x 1.8 x 0.3 cm. On examination, there were multiple pieces of tissue, one with fibrosis and clusters of mesh and inflammation with squamous mucosa, one with submucosal inflammation and mesh with fibers with giant cells. I noted mild-moderate inflammation in the mucosal piece and dense fibrosis. There was evidence of mesh degradation ("treebarking"). From my review of Ms. Bridges's medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Prolift Total and TVT-O were the cause of her exposure, urinary dysfunction, pelvic pain, dyspareunia, and revision surgery.

Carolyn Doyle was implanted with a Prolift Total for the treatment of uterovaginal prolapse on December 19, 2007. She developed erosion in the posterior vaginal wall (2 in. x 2 mm) and underwent revision surgery on February 18, 2011 by the implanting physician. Pathology was not available for review. Should pathology become available, I reserve the right to supplement my findings. She had a minor in-office excision procedure on May 23, 2011 without complication. On February 1, 2012, she underwent another revision under general anesthesia for mesh exposure (2 x 4 cm), cystocele and urinary retention. The pathology report from Cleveland Clinic has the following diagnosis: "Vagina, posterior wall foreign body, removal: benign squamous mucosa with ulceration and reactive changes and foreign body giant cell reaction associated with refractile foreign material, compatible with mesh." On examination of the pathology from the February 1, 2012 procedure, I noted: one piece with squamous mucosa with multiple clusters of mesh fibers with surrounding chronic inflammation and a ulceration/defect in mucosa overlying areas of dense inflammation (focally active) with mesh; a second piece with fibrosis and mesh fiber clusters with entrapped nerves. The inflammation was mild to moderate chronic inflammation. There was a foreign body giant cell response centered around the mesh fibers. There were ulcerated areas with neutrophils and plasma cells as well. There was dense fibrosis around and between the mesh fibers. There was evidence of degradation (treebarking). There were multiple small, mid-sized nerve entrapped in dense fibrosis in and around mesh fibers. From my review of Ms. Doyle's medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Prolift Total was the cause of her mesh exposure, pain, urinary/bladder dysfunction and resulting revision surgery.

Ann Fuller was implanted with Gynemesh for the surgical treatment of cystocele on October 10, 2007. Mesh was removed from the anterior in an in-office excision procedure on March 4, 2008 (1 x 1 cm). Ms. Fuller presented again later that year with vaginal mesh erosion and dyspareunia and on November 3, 2008, underwent a laparoscopic lysis of intra-abdominal and intrapelvic adhesion; right oophorectomy, and excision of eroded vaginal mesh. Pathology was not available for review. The pathology report states that only gross examination was performed of the specimen which consisted of multiple pieces of mesh measuring in aggregate 2.8 x 2.5 x 1.0

cm. Thereafter, Ms. Fuller was diagnosed with recurrent mesh erosion, chronic pelvic pain, urinary urgency, overactive bladder, dyspareunia, levator spasm and mixed stress and urge urinary incontinence. After treatment with physical therapy, Botox injections, trigger point injections and valium suppositories, Ms. Fuller underwent another mesh removal procedure on December 17, 2013. The pathology report noted three fragments of teal suture material and semi-translucent mesh (0.5 x 0.4 x 0.2 cm; 2.0 x 0.6 x 0.4 cm; and 1.9 x 0.7 x 0.4 cm). On examination, I noted two pieces of fibrous tissue with multiple clusters of mesh surrounded by foreign body giant cells, mild chronic inflammation and fibrosis. The fibrosis was dense around and between fibers. There was evidence of degradation in the form of treebarking around preserved mesh fibers and in mesh fiber produced spaces. I also noted a rare small nerve in the convoluted, scarred tissue. From my review of Ms. Fuller's medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Gynemesh was the cause of her mesh exposure, chronic pelvic pain, urinary/bladder dysfunction and resulting revision surgeries and medical treatments.

Amelia Gonzales was implanted with a Prolift+M Total on January 20, 2010 for the treatment of rectocele and urethrocystocele. On April 8, 2010, Ms. Gonzales was implanted with a TVT-Secure for the treatment of stress urinary incontinence. During the procedure, a small amount of granulation tissue was excised from the vaginal wall. The pathology report stated that microscopic sections of the vaginal granulation tissue (0.6 x0.5 x 0.1 cm) were examined but the description was omitted. On microscopic examination, I noted a single piece of granulation tissue with neutrophils, active and chronic inflammation. There was no mesh in the tissue sample submitted for microscopic examination. Ms. Gonzales presented in late 2011 with recurrent urinary tracts infections. An in-office cystoscopy on August 25, 2011 revealed that a 6 mm portion of the TVT-Secure sling had eroded into the right bladder neck area. Ms. Gonzales underwent a transurethral resection procedure to remove the mesh from the bladder on December 13, 2011. The pathology report describes the removed mesh as four fragments, measuring 0.8 x 0.8 cm in the aggregate. On examination, I noted fragments of scarred fibrotic tissue with focal dense chronic inflammation; one piece had a cauterized edge with detached mesh fiber. The tissue was densely fibrotic and scarred with small nerve fibers present in the fibrosis. From my review of Ms. Gonzalez's medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Prolift+M Total and TVT Secure were the cause of her mesh erosion, pain, urinary dysfunction, and resulting revision surgeries.

Debbie Joplin was implanted with a TVT-O for the treatment of stress urinary incontinence on September 18, 2006. Thereafter, she developed a perirectal fistula. On June 16, 2011, she underwent a removal procedure during which infected mesh was removed. She underwent another procedure on December 19, 2011 to address the perianal sinus extending to the perivaginal and periurethral area with mesh extrusion. Pathology from these two removal procedures are not available at this time. I reserve the right to supplement my report should such pathology become available. From my review of the medical records, it is my opinion that the TVT-O was the cause of Ms. Joplin's mesh extrusion and resulting removal surgeries.

Amy Holland was implanted with a Prolift Anterior for the treatment of cystocele and a TVT-O for the treatment of stress urinary incontinence on November 4, 2008. Ms. Holland presented with exposed mesh on the right side of the transverse vaginal incision and underwent a

revision of the Prolift mesh on February 3, 2009. The pathology report described the removed specimen as "surgical mesh inflamed granulation tissue and scar tissue with foreign body reaction, 5 x 8 mm." On examination, I noted multiple fragments – granulation tissue with active inflammation covered with mucosal ulcer and larger pieces of fibrotic tissue with dense inflammation centered around the mesh fibers. There was active inflammation in areas of granulation tissue; chronic inflammation around the mesh fibers in fibrosis; and foreign body giant cell response. There was dense fibrosis and scar. There was evidence of degradation (treebarking). Ms. Holland returned to the operating room on September 18, 2009 for mesh removal with complaints of dyspareunia and pelvic pain. The operative reports states that mesh was noted to be palpable in band-like form consistent with a sling toward the obturator spaces and that Prolift mesh towards the mid to proximal portion of the vagina was also palpable. The specimen sent to pathology consisted of "foreign plastic mesh material with blue suture overlying soft tissue measuring 0.8 x 0.7 x 0.3 cm." On examination, I noted a piece of tissue with dense fibrosis, small nerves, and focal mesh fibers. There were only two mesh fibers present in the tissue submitted for microscopic examination. There was minimal chronic inflammation and focal foreign body response. S100 staining revealed small mesh nerves entrapped in dense fibrosis. The mesh fiber was intact. From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Prolift Anterior and TVT-O were the cause of Ms. Holland's pelvic pain, dyspareunia, mesh erosion and resulting removal surgeries.

Mary Kilday was implanted with Prolift+M Posterior for rectocele and enterocele along with a vault suspension for vaginal vault prolapse on September 9, 2009. She presented in June 2010 with persistent dyspareunia and mild urge incontinence. On examination, there was a band of mesh from the upper portion of the left posterior wall towards the sacrospinous ligament with significant scarring which was tender on deep palpation. On June 16, 2010, Ms. Kilday underwent revision surgery during which a portion of the mesh arm was removed. According to the pathology report, the removed mesh measured 1.2 x 0.5 x 0.3 cm. On microscopic examination, I noted that the tissue submitted for microscopic examination consisted of 3 three pieces of tissue with a dense scar plate surrounding abundant mesh fibers. There was mild chronic inflammation and foreign body reaction around the mesh. Multiple nerves are present in the scar plate, some of which are distorted by and present in between mesh fibers. There was evidence of mesh degradation (treebarking). From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Prolift+M Posterior was the cause of Ms. Kilday's persistent dyspareunia and resulting removal surgery.

Kimberly Lager was implanted with a TVT-O for the treatment of stress urinary incontinence on July 12, 2007. In addition to the TVT-O procedure, Ms. Lager underwent a vaginal hysterectomy and anterior and posterior repair for uterine prolapse with cystocele and rectocele. Subsequently, Ms. Lager had a recurrence of cystocele and underwent an anterior colporrhaphy with Gynemesh PS on May 17, 2010. Ms. Lager presented with erosion of mesh in the distal anterior vaginal wall (1 cm) which was revised under general anesthesia on December 16, 2010. The pathology report states that the mesh specimen "consists of dark red vaginal mesh, measuring 1.5 x .5 cm." Pathology was not available for review. If it becomes available, I reserve the right to supplement my report. On August 11, 2011, Ms. Lager underwent another revision procedure for extruded and exposed mesh to the right of the midline on her anterior vaginal wall.

The pathology report describes the mesh specimen as "four pinkish irregular glistening fragments of soft tissue with adherent mesh-like material, 2.0 x 1.0 x 0.3 cm in aggregate." The pathological diagnosis in the report was as follows: "Reactive squamous mucosa, fibromuscular tissue with focal reactive fibrosis and foreign material consistent with history. There is a chronic inflammatory histiocytic infiltrate. There are no neoplastic changes." On my examination, I noted multiple pieces of tissue with clusters of mesh fibers and surrounding chronic and foreign body inflammation. The inflammation was mild to moderate chronic inflammation and there was giant cell reaction both of which were centered around the mesh fiber clusters. There was also dense scar/fibrosis around the mesh fibers. There was evidence of mesh degradation (treebarking). From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Gynemesh PS was the cause of Ms. Lager's persistent erosion and resulting removal surgeries.

Patti Phelps was implanted with a TVT for the treatment of stress urinary incontinence on July 12, 2000. In October 2005 and again in November 2008, Ms. Phelps presented with pressure in the vaginal area, pelvic pain, dyspareunia, bladder pain and pressure, and urinary leakage. Cystoscopy on December 11, 2008 showed mesh erosion. On January 22, 2009, Ms. Phelps underwent urethrolysis with urethroscopic transection of eroded mesh. Pathology was not available for this procedure. During a follow-up visit on February 5, 2009, urethroscopic examination revealed additional mesh erosion. Ms. Phelps underwent a second revision surgery on February 11, 2009. The pathology report provided the following gross description of removed mesh: "In formalin labeled "right sling resection" are four irregular fragments of grey-white to pink-red, glistening, rubbery soft tissue ranging from 0.9 x 0.3 x 0.2 cm to 2.0 x 0.7 x 0.1 cm. The largest fragment is bisected and the specimen is entirely submitted in 1 A." The pathology report contained the following diagnosis: "Right sling resection: Fibrous tissue with histiocytic reaction to polarizable foreign material. Benign squamous mucosa." On examination of samples submitted for microscopic examination from the removed mesh and surrounding tissue, I noted mucosal and submucosal tissue with abundant mesh fibers. There was mild chronic inflammation with foreign body reaction. There was dense fibrosis present around the mesh fibers. There was evidence of degradation (treebarking). S100 staining revealed multiple nerves entrapped in dense fibrosis around mesh fibers. In addition, there was fibrosis extending into the atrophic skeletal muscle. After the revision procedure, Ms. Phelps developed a urethrovaginal fistula which was repaired with an autologous sling on May 11, 2009. From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the TVT device was the cause of Ms. Phelps's erosion, dyspareunia, pelvic pain and pressure, bladder pain and pressure, and resulting surgical procedures for mesh removal and urethrovaginal fistula repair.

Maria Quijano was implanted with a TVT for stress incontinence on March 29, 2010. She later presented with erosion and dyspareunia. She underwent a mesh excision procedure and endocervical curettage for CIN2 cervical lesion on January 23, 2012. The pathology report indicates that mesh from the anterior vaginal wall was removed as well as tissue from the cervix and endocervix. I received 32 slides from the procedure but each appear to be from the cervical tissue. I have requested that slides be cut from the removed mesh. Should additional slides be made available, I reserve the right to supplement my report. From my review of the medical

records and the pathology report, it is my opinion that the TVT device was a substantial contributing cause of Ms. Quijano's erosion and resulting mesh removal procedure.

Rhoda Schachtman was implanted with a Prolift Total for the treatment of cystocele and rectocele and a TVT for stress urinary incontinence on February 7, 2008. Following implant, Ms. Schachtman developed erosion of the anterior mesh arm, prolapse, urgency, frequency, urinary retention, urinary leakage, and pelvic pain and pressure. On February 14, 2012, she underwent a mesh revision procedure to remove the eroded mesh and address the recurrent prolapse. The pathology report provides the following gross examination: two pieces of soft tissue and mesh measuring 0.5 x 0.7 x 0.3 cm and 3.6 x 1.5 x 0.5 cm. On my examination, I noted two pieces of scarred fibrous tissue with multiple clusters of mesh fibers with foreign body giant cell reaction and mild chronic inflammation. There was dense fibrosis and scarring. There was evidence of degradation (treebarking). S100 slides revealed multiple small to mid-sized nerves entrapped in fibrosis in between and around mesh fibers. From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Prolift Total was the cause of Ms. Schachtman's erosion, urinary dysfunction, and resulting removal procedure.

Deanna Thomas was implanted with Gynemesh for the treatment of pelvic organ prolapse and a TVT for the treatment of stress urinary incontinence on December 10, 2009. On October 20, 2010, Ms. Thomas presented pre-operatively with complaints of significant pain and recurrent prolapse. On examination, the anterior mesh was revealed to be displaced "into a bunched up wad." On October 25, 2010, the bunched mesh material was surgically removed. Following the mesh removal, the Elevate graft system was placed to address the recurrent prolapse; a TVT-O was implanted to address likely onset of stress urinary incontinence after the procedure. The pathology report provides the following gross description of the removed Gynemesh: "two irregular, focally ragged fragments of sutured tan-red tissue which together measure 4.0 x 3.0 x up to 0.7 cm. The cut surfaces feature embedded blue sutures." On examination of the tissue submitted for microscopic examination, I noted two pieces of tissue with dense fibrosis/scar surrounding clusters of mesh fibers. There was mild chronic inflammation and foreign body giant cell reaction around fibers. There was evidence of degradation (treebarking). S100 staining revealed nerves entrapped in scar adjacent to mesh. From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Gynemesh was the cause of Ms. Thomas's mesh displacement/mesh bunching, pelvic pain, and resulting removal procedure.

Lisa Thompson was implanted with a TVT-O for the treatment of stress urinary incontinence on February 20, 2009. Following the implant, she experienced worsening dyspareunia and developed erosion. On May 1, 2009, Ms. Thompson underwent a procedure under general anesthesia to re-approximate the vaginal mucosa over the area of exposed mesh. The TVT-O became exposed again and she returned to the OR for a second revision on June 2, 2009. Pathology was not available for review. Should pathology become available, I reserve the right to supplement my findings. In March 2010, Ms. Thompson presented with dyspareunia, urgency, mixed incontinence, urinary retention, and nocturia. On exam, there was tenderness along the vaginal wall. On June 25, 2010, Ms. Thompson underwent a third procedure under general anesthesia during which mesh was removed. The operative report notes extensive scarring

underneath and along the sides of the urethra. The pathology report under "MACROSCOPIC EXAMINATION:" contains the following description for the mesh specimen: "Received in a container of formalin and designated "Thompson, Lisa - Mesh". The specimen consists of a red, tan, and gray pliable irregular fragment of tissue within which is identified abundant wiry blue filament. The tissue measures 2.5 x 0.9 x 0.3 cm. The specimen is grossly consistent with a foreign body mesh. The specimen is for gross examination only." On examination of tissue submitted for microscopic examination, I noted squamous mucosa, large pieces with deep submucosal fibrosis. No mesh fibers were present in this sample. There was minimal inflammation. There was dense fibrosis at the deep aspect of the excision. Should additional slides from this procedure be made available to me, I reserve the right to supplement my report. From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the TVT-O was more likely than not the cause of Ms. Thompson's exposure, dyspareunia secondary to exposure, urinary retention, and multiple excision procedures.

Jennifer Van Rensburg was implanted with Prolift Total for cystocele and rectocele and TVT-Secur for the treatment of recurrent stress urinary incontinence on February 5, 2008. On January 25, 2011, she presented with erosion. The operative report states that erosion was not present on the anterior vaginal wall, but there was "extensive mesh erosion with blue mesh and thick white material extruded through her posterior fourchette." The exposed mesh on the posterior wall was excised. The pathology report provides the following gross description: "fragments of wire mesh with a small amount of attached soft dark red tissue. The specimen aggregates 2.0 x 0.5 x 0.3 cm. No sections are submitted." Pathology from this excision procedure was not available. Should pathology become available, I reserve the right to supplement my report. Ms. Van Rensburg developed urinary dysfunction symptoms such as urge, overactive bladder, and incomplete emptying with persistent vaginal pain. On May 7, 2014, she returned to the OR for revision. The operative report notes that the anterior vaginal graft was palpable but not visible and that there was significant vaginal scarring. The anterior portion of the Prolift Total was excised all the way to the obturator foramen on both sides. The TVT-Secur was incised at the midline, dissected laterally to the perivaginal sulcus, and removed. The pathology report describes anterior vaginal wall mesh in three portions measuring 7.0 x 4.0 x 1.3 cm in the aggregate. On examination, I noted one piece of tissue with dense scar around clusters of mesh fibers. There was mild chronic inflammation and foreign body giant cell reaction around fibers. There was dense fibrosis/scar around the mesh fibers. There was evidence of degradation (treebarking). From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Prolift Total and TVT-Secur were the cause of Ms. Van Rensburg's mesh exposure, urinary dysfunction, persistent vaginal pain, and resulting excision procedures.

Mary Wise was implanted with the Prolift+M Total for the treatment of cystocele, vaginal vault prolapse, and rectocele and TVT for the treatment of stress urinary incontinence on December 17, 2009. Ms. Wise developed mesh banding at the apex of the vagina, post-menopausal bleeding, recurrent rectocele, and dyspareunia. She returned to the OR on January 19, 2012 for hysteroscopy with dilation and curettage, exploratory anterior colpotomy with excision of portion of vaginal mesh, and rectocele repair. The operative report notes palpable banding of mesh at the site of patient's tenderness. There was significant distensibility of the posterior vaginal mesh. Mesh was removed from the anterior and posterior vagina. Both mesh and

endometrial curettage were sent to pathology. The pathology report contains the following gross description: “B. The specimen is received in formalin and is additionally labeled with "vaginal mesh" and consists of tan mesh tissue, measuring 1.0 x 0.6 x 0.4 cm. Sectioning reveals tan mesh and tan-red soft tissue. . . . C. The specimen is received in formalin and is additionally labeled with "posterior vaginal epithelium" and consists of white epithelial tissue, measuring 4.0 x 1.0 x 0.4 cm. Sectioning reveals a tan-white fibrous tissue with no definitive lesions identified. The resection margin is inked blue.” The tissue submitted for microscopic examination and provided to me for review – Parts A, B, and C – did not contain mesh. They were composed of endometrium, ectocervical and endocervical mucosa, minute fibrous tissue (NSA), and squamous mucosa with subnormal mucosa. Should specimens with mesh become available, I reserve the right to supplement my report. Thereafter, Ms. Wise presented for pre-operative evaluation on October 12, 2015, with the following active problems: bladder sphincter spasm, dyspareunia, hernia of rectum into the vaginal and bowel incontinence. On exam, erosion was identified. Ms. Wise underwent a revision procedure on October 20, 2015. According to the operative report, “the mesh appears clinically to have contracted with the majority of the mesh left at the top of the vagina.” The operative report states that there is definite banding present upon palpation which produces pain. Dense mesh banding was noted to be present from “sidewall to sidewall.” The mesh was dissected out as much as could be removed. The pathology report notes that the mesh specimen measured 6.6 x 3.1 x 0.2 cm. On microscopic examination of submitted tissue samples, I noted mesh fibers in dense scar with surrounding chronic mild-moderate inflammation and foreign body giant cell reaction. There was abundant scar and fibrosis. There was evidence of degradation (treebarking). There were multiple nerves present, some entrapped next to mesh. From my review of the medical records and my pathological findings as described here and in Exhibit C, it is my opinion that the Prolift+M Total was the cause of Ms. Wise’s persistent mesh exposures, pelvic pain, dyspareunia and resulting removal procedures.

Additional Disclosures

I may be asked to review additional materials and/or documentation as the cases progress and, in that event, I will supplement this report.

Exhibits which I plan to use as a summary of or in support of my opinions are as follows:

1. Materials listed in **Exhibit B** and any materials identified in this report. Any additional materials to be used will be timely disclosed;

2. Spreadsheet of detailed pathology reports (**Exhibit C)**;

3. Photomicrographs of pathology I and others have reviewed (**Exhibit D)**;

4. Any exhibit identified at any deposition taken in MDL 2327; and

5. All exhibits referenced in this report.

My qualifications and Curriculum Vitae are attached hereto and by reference made a part

hereof. Please see **Exhibit A** attached hereto.

The compensation per hour which I expect to be paid for my review, study and testimony is $685 per hour.

I previously testified as an expert in the following cases:

Bradford v. North West Radiology	(WA State Ct.)
Lynda Barner, et a. v. C.R. Bard, Inc.	2:11-CV-00055
Tammy M. Lambert, et al. v. C.R. Bard, Inc.	2:14-CV-12092
Patsy Luttrell v. C.R. Bard, Inc.	2:13-CV-03151
Saundra Nevels, et al. v. C.R. Bard, Inc.	2:13-CV-01024
Beverly Pennington, et al. v. C.R. Bard, Inc.	2:11-CV-00010
Deborah White, et al. v. C.R. Bard, Inc.	2:11-CV-00234
Betty Adkins, et al.	2:10-CV-00824
Aricia Blake, et al.	2:10-CV-01380
Doris H. Callen, et al. v. C.R. Bard, Inc.	2:14-CV-14375
Deanna Lynn Fredericks v. C.R. Bard, Inc.	2:13-CV-02976
Karen Huber v. C.R. Bard, Inc.	2:13-CV-02424
Janet McNally, et al.	2:10-CV-01215
Martha Smitty, et al. v. C.R. Bard, Inc.	2:13-CV-33750

This 1st day of February, 2016.

Kimberly H. Allison, M.D.